ABBOTT

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Ref: **Docket No 2005D-0174 – Draft Guidance on Expiration Dating of Unit-Dose Repackaged Drugs**

To Whom it May Concern:

Abbott is very pleased to have the opportunity to provide comments on the Draft Guidance on Expiration Dating of Unit-Dose Repackaged Drugs published on May 31, 2005 in the *Federal Register*.

We thank the Food and Drug Administration for your consideration of our comments. Should you have any questions, please contact Kathy Wessberg (tel: 847-938-1264, e-mail: kathy.wessberg@abbott.com).

Sincerely,

Richard M. Johnson
Encl: Comments

September 1, 2005

ABBOTT COMMENTS TO FDA ON

Docket No. 2005D-0174

COMMENTS

Specific Comments:

III. Discussion:

Proposed change:
Add to the paragraph after point #4 that if the repackager uses a container / closure system that is not equivalent to the manufacturer's market package that the repackager bears responsibility for determining stability of the new container/closure system.

Change text as highlight in **bold**:
At the end of the paragraph in point #4 add:

"If the repackager does not use a container closure system equivalent to the manufacturer's market package, then the repackager must generate stability data for the drug product in the new container-closure system to justify the expiration date or BUD used."

Reason:
Statement should be added to be consistent with USP <1178> Good Repackaging Practices and FDA Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics Chemistry, Manufacturing and Controls Documentation which states: "A repackager is a firm that buys drug product from the drug product manufacturer or distributor and repackages it for sale under a label different from that of the manufacturer. The repackager is responsible for ensuring the quality and stability of the repackaged drug product."